

**LETTER OF ANNOUNCEMENT**  
*Letter of Adhesion*

7 November 2018

Dear On-boarding Partner,

EMVO recently announced that the new Participation Agreement (“**PA**”) between EMVO and the On-boarding Partners for the Operational Phase is now available on the On-boarding Partner Portal (“**OBP Portal**”) governing your participation in the full-scale operational mode of the European Medicines Verification System (“**Operational Phase**”).

In the light of the above, EMVO hereby informs you that the two Letter of Adhesion Templates are now available on the EMVO website.

The Letter of Adhesion is a letter signed by a Marketing Authorisation Holder (“**MAH**”) and addressed to the On-boarding Partner that represents the MAH with regards to the data upload onto the European Hub.

It constitutes the written statement by which the MAH (i) adheres to the PA between EMVO and the On-boarding Partner, (ii) agrees to be bound by the same obligations as the On-boarding Partner and (iii) agrees to be jointly and severally liable with the On-boarding Partner vis-à-vis EMVO. Via this letter, the MAH also confirms that it authorises the On-boarding Partner to upload its data on the European Hub on its behalf, as well as that it qualifies as its affiliate as per the ‘Affiliate’ definition set out in the PA. As a result, any termination of the PA will automatically lead to the termination of the MAH’s adhesion to it.

EMVO would also like to draw your attention to the fact that there are two types of Letters of Adhesion: (i) one for On-boarding Partners located in the European Economic Area and (ii) one for On-boarding Partners located outside the European Economic Area (“**EEA**”)¹. Both types have the same above-mentioned content, while the non-EEA type includes additional safeguards for the protection of the uploaded data as described in Appendix 4 of the PA².

<sup>1</sup> The European Economic Area (EEA) unites the EU Member States, Iceland, Liechtenstein, and Norway. Therefore, countries like Switzerland, United States, Israel, Australia etc do not belong to the EEA and the On-boarding Partners established in these countries are required to sign the Letter of Adhesion for non-EEA Onboarding Partners.

<sup>2</sup> Only On-boarding Partners established outside the EEA are required to sign Appendix 4 of the Participation Agreement and comply with the provisions thereunder.



In the event of any question or uncertainty, please do not hesitate to contact our Helpdesk:

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## **EMVO Team**

### **European Medicines Verification Organisation**

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